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Acasti Announces Fourth Quarter and Fiscal Year Results

LAVAL, Quebec, May 21, 2014 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("**Acasti**" or the "**Corporation**") (Nasdaq:ACST) (TSX-V:APO), an emerging biopharmaceutical company focused on the research, development and commercialization of new krill oil-based forms of omega-3 phospholipid therapies for the treatment and prevention of certain cardiometabolic disorders, announces its consolidated financial results for the fourth quarter and fiscal year ended February 28, 2014.

Financial Results: Fourth Quarter Ended February 28, 2014

- Revenues were \$201,000 for the quarter ended February 28, 2014, versus \$49,000 for the quarter ended February 28, 2013. Sales in both years were generated from the commercialization of Onemia[®], the Corporation's medical food product
- Research and development (R&D) expenses were \$714,000 for the quarter, down from \$918,000 in the prior year
- Adjusted EBITDA was negative \$(977,000) for the quarter, versus negative \$(1,373,000) in the prior year
- Net loss was \$(2,553,000) for the quarter, versus a net loss of \$(1,952,000) in the prior year.

The year-over-year improvement in adjusted EBITDA is largely due to lower R&D expenses. As well, general & administrative expenses were down due to lower professional fees and royalties, with Acasti now being royalty free from Neptune.

The increase in the year-over-year net loss is largely due to higher depreciation and amortization expenses, following an increase in the Corporation's licensed asset, resulting from the royalty prepayment agreement with Neptune, and higher stock based compensation expenses.

Financial Results: Fiscal Year ended February 28, 2014

- Revenues were \$501,000 for the fiscal year ended February 28, 2014, versus \$724,000 for the year ended February 28, 2013. Sales in both years were generated from the commercialization of Onemia[®], the Corporation's medical food product
- Research and development expenses were \$4,297,000 for the year, up from \$3,009,000 in the prior year
- Adjusted EBITDA was negative \$(5,584,000) for the year, versus negative \$(4,397,000) in the prior year
- A net loss of \$(11,612,000) or \$(0.14) per share was recorded for the year, versus a net loss of \$(6,892,000) or \$(0.09) per share in the prior year.

Research and development expenses were up over the prior year due to an increase in contract expenses related to Acasti's clinical trials.

The year-over-year decline in adjusted EBITDA was driven by the higher R&D expenses described above.

The higher net loss over the prior year was largely due to expense increases related to depreciation and amortization, stock based compensation and R&D.

"Over the past year, we continued to strengthen our business, and focus our efforts on moving closer to securing regulatory approval for our investigational new drug candidate, CaPre®," said Pierre Lemieux, Acasti's Chief Operating Officer. "We actively advanced our research and clinical development program, secured a manufacturing agreement for CaPre® clinical material, successfully completed a major financing and defended and strengthened our intellectual property. These successes are a testimony to our commitment to lay the groundwork for future growth and create sustained shareholder value by further positioning Acasti as a leader in pharmaceutical grade omega-3 phospholipids. There remain a number of important milestones ahead. However, with the encouraging results seen to date, a strong team, a solid balance sheet and a firm drive to succeed, we are well positioned to seize the opportunities before us."

Clinical Trials

Phase II TRIFECTA Trial

The number of targeted patients evaluable as per protocol has been reached. Acasti is currently evaluating the efficacy and safety of CaPre® for the treatment of patients with mild to severe hypertriglyceridemia, which is the primary objective of the study. The secondary objective of evaluating if statistically significant efficacy was reached in patient populations with mild to moderate (triglyceride levels ranging from 200 to 499 mg/dL) and severe hypertriglyceridemia (triglyceride levels over 500 mg/dL) will also be assessed separately. Based on patient information currently available, the Corporation does not believe the sample size is large enough to conclude the efficacy of CaPre in treating severe hypertriglyceridemia as part of the TRIFECTA trial. Based on literature, Acasti does not expect the FDA to request efficacy data on patients with severe hypertriglyceridemia before granting permission to conduct a Phase III trial. Acasti is targeting trial completion by the end of the second quarter of calendar 2014 and results will be available at a future date yet to be determined.

Pharmacokinetic (PK) Trial

As previously announced the US Food and Drug Administration (FDA) gave Acasti clearance to initiate a PK trial in the US. The trial is underway and is expected to be completed by the end of the second quarter of calendar 2014, with results being announced in the following quarter.

Phase 3 Trial

Concurrently with the PK trial, the Corporation is corresponding with the FDA and has responded to their recommendations regarding Acasti's upcoming Investigational New Drug

(IND) filing for a pivotal Phase III clinical trial of CaPre® in the US. The FDA has invited Acasti to formally request an end of Phase II/pre Phase III meeting to allow them to provide feedback on the submission and to address specific questions for which Acasti is seeking a buy-in and final response from the FDA. Acasti intends to do this as soon as TRIFECTA trial results are available.

With the FDA's recent decision to not grant authorization to commercialize Acasti competitors' drugs in the mild to moderate patient population before the demonstration of clinical outcome benefits, Acasti is reassessing its clinical strategy and may put a primary and first focus on the severe hypertriglyceridemia population.

[About Acasti Pharma Inc.](#)

Acasti is an emerging biopharmaceutical company focused on the research, development and commercialization of new krill oil-based forms of omega-3 phospholipid therapies for the treatment and prevention of certain cardiometabolic disorders, in particular abnormalities in blood lipids, also known as dyslipidemia. Because krill feeds on phytoplankton (diatoms and dinoflagellates), it is a major source of phospholipids and polyunsaturated fatty acids ("PUFAs"), mainly eicosapentaenoic acid ("EPA") and docosahexaenoic acid ("DHA"), which are two types of omega-3 fatty acids well known to be beneficial for human health. CaPre®, currently Acasti's only prescription drug candidate, is a highly purified omega-3 phospholipid concentrate derived from krill oil and is being developed to help prevent and treat hypertriglyceridemia, which is a condition characterized by abnormally high levels of triglycerides in the bloodstream. ONEMIA®, a medical food and currently Acasti's only commercialized product, is a purified omega-3 phospholipid concentrate derived from krill oil with lower levels of phospholipids, EPA and DHA content than CaPre®.

Forward Looking Statements

Certain statements included in this press release may be considered forward-looking information within the meaning of Canadian securities laws and forward-looking statements within the meaning of U.S. federal securities laws, both of which we refer to as forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties, and other unknown factors that could cause the actual results of Acasti to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. In addition to statements which explicitly describe such risks and uncertainties, readers are urged to consider statements labeled with the terms "believes," "belief," "expects," "intends," "anticipates," "will," or "plans" to be uncertain and forward-looking. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. The forward-looking statements contained herein are also subject generally to other risks and uncertainties that are described from time to time in Acasti's public securities filings with the Securities and Exchange Commission and the Canadian securities commissions. Except as required by law, Acasti disclaims any intention or obligation to update or revise any forward-looking statements.

Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Due to risks and uncertainties, including the risks and uncertainties identified by Acasti in its public securities filings available at www.sedar.com and www.sec.gov/edgar.shtml, actual events may differ

materially from current expectations. Except as required by law, Acasti disclaims any intention or obligation to update or revise any forward-looking statements.

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